MAR - 7 2012 K113372

SECTION 7 - 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter Name & Address:	Corventis, Inc. 1410 Energy Park Drive, Suite 1 St. Paul, MN 55108
Contact Person:	Michele Chin-Purcell, Ph.D. 651-925-3803 (phone) 651-389-3251 (fax)
Trade/Proprietary Name:	NUVANT® Mobile Cardiac Telemetry System
Common/Usual Name:	Mobile Cardiac Telemetry System
Classification Name:	Arrhythmia Detector and Alarm (21 CFR 870.1025, Product Code DSI) Patient Physiological Monitor (with arrhythmia detection) (21 CFR 870.1025, Product Code MHX)
Class:	Class II, Special Controls
510(k):	Special 510(k)
Date Prepared:	November 15, 2011

Predicate Device:

NUVANT Mobile Cardiac Telemetry System, Corventis, Inc. cleared by FDA under 510(k) number K111917; 21 CFR 870.1025, DSI "Arrhythmia Detector and Alarm", and 21 CFR 870.1025, MHX "Patient Physiological Monitor (with arrhythmia detection)"

(Hereafter referred to as the "predicate NUVANT".)

BACKGROUND INFORMATION

The following is the subject device of this Special 510(k):

- The NUVANT Mobile Cardiac Telemetry System (hereafter referred to as "subject NUVANT")

This Special 510(k) proposes to add a framework that will reserve space for recording ECG strips for each event type; limiting the redundant recording of certain event types.

This change does not change to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and does not affect the safety and effectiveness of the device when used as labeled [807.92(a)(5)]. The indications for use of the subject NUVANT are unchanged from the predicate NUVANT. The modification does not impact the fundamental scientific technology of the device.

INDICATION FOR USE STATEMENT

The following are the indications for use for the subject NUVANT. **These are unchanged from the predicate NUVANT:**

The NUVANT Mobile Cardiac Telemetry (MCT) System is intended to continuously measure, record, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias and conduction disorders.

The NUVANT system model monitors, derives and displays:

- *ECG*
- *Heart rate*

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TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The NUVANT MCT System is a wearable, wireless arrhythmia detection system that is used by clinicians to identify suspected cardiac arrhythmias. In combination with interpretation services provided by learned intermediaries in the Corventis Monitoring Center as well as online review of data (for prescribing physicians only), NUVANT MCT enables arrhythmia detection for up to 7.5 days for each PiiX application.

The NUVANT system components are:

- PiiX® (aka: Adherent Device) - a patient-worn device which is applied to the patient's torso. It contains the ECG electrodes for recording ECG and heart rate data.
- Patient Trigger Magnet - used by the patient to manually trigger the ECG collection when he/she experiences symptoms.
- zLink® (aka: Gateway) – hand-held device that receives information from the PiiX and transmits it to the Corventis Server via cellular technology.
- Server - The Server receives sensor data from the PiiX via zLink. ECG and heart rate are presented to learned intermediaries, Corventis cardiographic technicians, who prepare and deliver the information to prescribing physicians

The communication between the PiiX and the zLink is enabled via BlueTooth Technology. Sensor data and ECGs collected by the PiiX are transmitted to the Server via zLink.

The system components of the subject NUVANT are identical to the system components of the predicate NUVANT.

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PREDICATE DEVICES

The predicate device is:

NUVANT Mobile Cardiac Telemetry System, Corventis, Inc. cleared by FDA under 510(k) number K111917; 21 CFR 870.1025, DSI "Arrhythmia Detector and Alarm", and 21 CFR 870.1025, MHX "Patient Physiological Monitor (with arrhythmia detection)"

The following table summarizes the compared features and the predicate device.

Features comparison and corresponding predicate devices

Features being compared	Subject Devices	Predicate Devices
All technical features	Subject NUVANT	Predicate NUVANT (K111971)
Indications for Use	Subject NUVANT	Predicate NUVANT (K111917)

SUMMARY OF PERFORMACE TESTING

Both the subject and predicate NUVANT MCT meet the requirements of following performance standards in accordance with *FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm.*

IEC 60601-1

Medical Electrical Equipment – Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

IEC 60601-1-2

Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004))

AAMI/ANSI EC38

Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems, 2007.

AAMI/ANSI EC57

Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms, 1998/(R) 2008

CONCLUSION

The modifications proposed in the subject NUVANT System do not change the indications for use and do not change the fundamental scientific technology or use of the devices. As supported by the descriptive information and the bench tests, it is concluded that the subject NUVANT Mobile Cardiac Telemetry (NUVANT) System is as safe and as effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 7 2012

Corventis, Inc
c/o Ms. Kathy Lundberg
Vice President, QA, RA, Clinicals.
1410 Energy Park Dr. Suite 1
St. Paul. MN 55108

Re: K113372
Trade/Device Name: Nuvant, mobile cardiac telemetry
Regulation Number: 21 CFR 878.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX, DSI
Dated: February 7, 2011
Received: February 8, 2011

Dear Ms. Lundberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

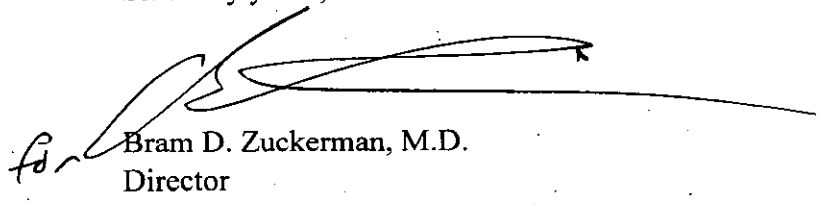
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): N/A K113372

Device Name: NUVANT® Mobile Cardiac Telemetry

Indications for Use:

The NUVANT Mobile Cardiac Telemetry (MCT) System is intended to continuously measure, record and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias and conduction disorders.

The NUVANT system model monitors, derives and displays:

- ECG
- Heart Rate

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113372

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